E. coli O157H7 and other Non-O157 STEC Sampling Program

Chapter 1 General

I. Purpose

This sampling program is part of VT Agency of Agriculture's raw product verification sampling program, and is a means of sampling non-intact beef or intact raw beef product intended to produce non-intact beef. VAAFM tests all raw beef samples collected under the routine and follow-up sampling programs for *E. coli* O157:H7 and *Salmonella*. VAAFM also tests beef manufacturing trimmings from cattle slaughtered onsite for non-O157 STEC serogroups (O26, O45, O103, O111, O121, and O145) and *Salmonella* to help ensure the protection of public health.

NOTE: For the purposes of this directive, when the directive references "raw beef" it includes veal and not-ready-to-eat (NRTE) beef.

II. Background

Non-intact beef components, and intact raw beef components that are intended to be processed into non-intact products, which contain *E. coli* O157H7 or non-*E. coli* O157H7 STEC serogroups (O26, O45, O103, O111, O121, and O145) are considered adulterated unless further processed using a procedure validated to destroy the pathogen. VAAFM sampling verifies that an establishment's controls or food safety procedures adequately address STEC. Therefore, as part of a risk based sampling program, these products will be the focus of VT's *E. coli* O157H7 and other non- *E. coli* O157H7 STEC sampling program. VAAFM requires establishments to hold or maintain control of raw beef products that VAAFM has tested for STEC pending negative results.

III. Changes

A. When IPP receive a sample request for beef manufacturing trimmings from cattle slaughtered on-site, they are to continue to follow the instructions in VT Directive 10,010.1 Rev. 4, and this document for collecting samples.
B. There are not changes to product sampling eligibility or sample collection procedures. There is optional updated training materials on collecting raw beef samples: https://www.youtube.com/watch?v=BlV_GpoTpUU&feature=youtu.be
C. Collect raw beef samples sent to a receiving establishment to be treated with an intervention that does not achieve a full lethality (i.e., less than a 5-log reduction for

Salmonella) at the receiving establishment where the intervention is applied, not at the originating establishment.

D. The non-O157H7 STEC samples will continue to be sent out-of-state for testing. See Sample Submission (below) and VT Directive 40-12 for more details.

At a later date, non-O157 STEC testing in other sampling programs will be implemented. FSIS will issue both a *Federal Register* notice and an FSIS Notice reflecting these changes before testing begins in these additional raw beef products for the six non-O157 STECs.

CHAPTER II – ELIGIBILITY CRITERIA FOR STEC SAMPLING

I. TERMINOLOGY

A. Ground Beef Products: Raw beef food products are sampled that meet the standards of identity for ground and chopped beef (9 CFR 319.15(a)), hamburger (9 CFR 319.15(b)), and beef patties (9 CFR 319.15(c)). In addition, the Agency will begin sampling product that contains a mixture of ground beef and non-beef species, unless the establishment labels the product in a manner to show that beef is not the predominant species in the product.

1. Raw ground beef products include:

    a. raw ground or chopped beef;

    b. hamburger;

    c. ground or chopped veal;

NOTE: For purposes of this directive, when the directive references beef, veal is included.

    d. veal or beef patties;

    e. veal or beef patty mix; and

    f. ground veal or beef product with added seasonings.

B. Raw Ground Beef and Patty Components

1. Beef Manufacturing Trimmings are:

Two piece chucks (i.e., the blade portion and an arm roast from the forequarter individually packaged and placed into the same container), raw beef source materials

from subprimal cuts (e.g., steaks and roasts) or primal cuts (e.g., round, loin, rib and other primals listed in 9 CFR 316.9, or boxed beef parts of boneless beef that establishments frequently use as components of raw ground beef.

2. Raw Ground Beef Components, Including Raw Beef Patty Components, Other Than Beef Manufacturing Trimmings are:

Raw esophagus (weasand) meat, head meat, cheek meat, beef from AMR systems (see definition 3. below), low temperature rendered (see definition 4. below) LFTB, partially defatted chopped beef, partially defatted beef fatty tissue, and heart meat.

3. A beef AMR system is a mechanical process separating skeletal muscle tissue from bones of livestock other than skulls or vertebral column bones of cattle ≥ 30 months of age, in accordance with 9 CFR 318.24.

NOTE: Establishments may label the resulting product from beef AMR systems as beef.

4. Low Temperature Rendering:

a. removal of lean from fat or very fat trimmings using heat; or

b. a centrifugation, drum drying process for boneless beef fatty tissue.

NOTE: Establishments may label the resulting product as “Lean Beef Trimmings, Finely Textured,” “Lean Beef Blocks, Derived from Beef Trimmings,” or “Lean Beef Chips, Derived from Beef Trimmings.”

II. SAMPLING

A. IPP are to be aware that VAAFM samples and tests eligible raw beef products produced under inspection, including inspected source materials that are subsequently used in retail operations conducted onsite.

B. Establishments that slaughter and further process raw beef product may be eligible for multiple VAAFM STEC sampling programs. These establishments may produce ground product, beef manufacturing trimmings, bench trim, and other raw ground beef or beef patty components. These establishments may use purchased product to produce bench trim or raw non-intact products. Therefore, IPP may receive multiple sample requests.

C. Some slaughter establishments may produce beef manufacturing trimmings and other raw ground beef components and grind that product or produce other raw non-intact product. In this situation, IPP are to sample the trim under the Beef manufacturing trimmings sampling program,

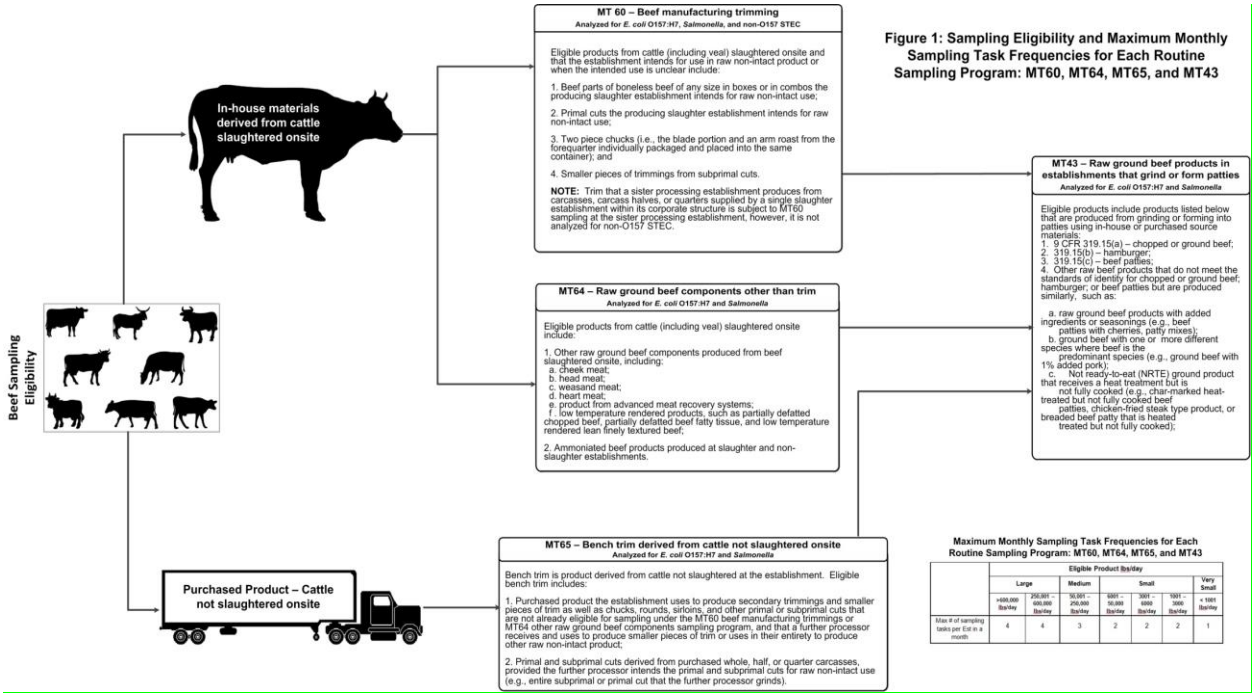
the other components as other raw ground beef components, and raw ground beef product under the raw ground beef sampling program when they receive sampling requests with these codes.

D. Establishments are eligible for both the Bench Trim and Beef Manufacturing Trimmings sampling programs if they use certain types of purchased product to produce bench trim and source materials from their own slaughter operation to produce beef manufacturing trimmings (see Figure 1 of this chapter).

E. Figure 1 on the following page provides a general description of eligible products for each of the routine domestic sampling programs. IPP are to refer to this figure, as needed, when they receive routine domestic sampling tasks.

F. As noted on Figure 1, VAAFM tests all raw beef samples collected under routine and follow-up sampling programs for *E. coli O157:H7* and *Salmonella*. VAAFM also tests beef manufacturing trimmings from cattle slaughtered on-site for non-O157 STEC.

NOTE: Trim that a sister processing establishment produces from carcasses, carcass halves, or quarters supplied by a single slaughter establishment within its corporate structure is subject to Beef Manufacturing Trimmings sampling at the sister processing establishment, however, it is not tested for non-O157 STEC because the trimmings are not generated from cattle slaughtered on-site.



Products Not Subject To Regulatory Sampling

Fabricated steaks and finely sliced beef (9 CFR 319.15(d)) do not meet the standard of identity for ground or chopped beef product and, therefore, would not be subject to *E. coli* O157:H7 sampling.
Raw beef sausage products are not subject to *E. coli* O157:H7 sampling and testing. –Per notice 39-14, the components of raw beef sausage are subject to sampling.
Ground buffalo or bison is also not a raw ground beef product subject to this verification sampling.

Table 1 below provides a general description for each of the domestic follow-up sampling programs. In the event of a positive sample from any of the routine domestic sampling programs, follow-up samples will be scheduled at the establishment. The purpose of scheduling these follow-up samples is to determine whether the establishment effectively addresses STEC.

Sampling Program	**Description**
Raw Ground Beef Product	Follow-up sampling of raw ground beef product in response to a raw ground beef positive result in raw ground beef product
Suppliers of beef manufacturing trimmings or other components from originating slaughter suppliers	Follow- up sampling at suppliers of beef manufacturing trimmings or other components from originating slaughter suppliers, in response to a raw ground beef or Bench trim positive result
Establishment that produced product	Follow-up sampling of trim or other components at the establishment that produced product in response to a beef manufacturing trimmings, bench trim, or other raw ground beef components testing positive

II. SAMPLING FREQUENCIES FOR ROUTINE SAMPLING PROGRAMS

A. IPP are to be aware that VAAFM has a set minimum sampling frequency for each establishment. VAAFM will sample each establishment that:

1. Produces raw ground beef products at least three times per year; and

2. Produces bench trim, other raw ground beef components, or beef manufacturing trimmings at least once per year for each product.

3. The frequency will be based on FSIS' Guidance to the states on the average frequency of testing done at very small federal establishments. In addition, VT reserves the right to alter the frequency at any given establishment based on information from, but not limited to, inspection activity, sampling results, and food safety assessments, in order to tailor the E. coli O157H7 or non-O157H7 STEC verification sampling program to address any perceived increase in risk.

4. The testing schedule for E. coli O157H7 in raw beef and non-O157H7 STEC in beef manufacturing trimmings will be determined for the period of October through September, and recorded on a spreadsheet.

5. Sampling is expected to be based on factors that may influence prevalence of and exposure to *E. coli* O157:H7, such as the volume of production of raw ground beef products, season of the year, and the number of suppliers for an establishment. The FSIS risk assessment on *E. coli* O157:H7 has determined that volume of production is a better determinant of the risk of *E. coli* O157:H7 than size of the establishment. It also determined that the prevalence of *E. coli* O157:H7 in cattle, and the incidence of foodborne illness and of products positive for *E. coli* O157:H7 are higher during the warmer months. Therefore, an establishment producing a large volume of ground beef products will likely be sampled more frequently than an establishment producing a lower volume of raw ground beef products. Likewise, there will an increase in sampling during the high prevalence season/warmer months in VT

III. INTENDED USE AND SAMPLING ELIGIBILITY

A. The product's intended use is a key factor in determining whether VAAFM collects samples. VAAFM samples products intended for use in raw non-intact product (e.g., ground, mechanically tenderized, needled, and vacuum marinated), or when the intended use is unclear.

B. IPP are not to sample product that the establishment intends for use in intact or ready-to-eat product, or product that will receive other full lethality treatment at another state inspected establishment. If the product is to receive a full lethality treatment at another state inspected establishment, IPP are to verify that the establishment's hazard analysis and flow chart show that the product is intended for one of these controlled uses, and that the establishment has controls that ensure that the product is used as intended. If not, IPP are to collect the sample. Examples of full lethality treatments other than cooking can include high pressure processing and irradiation, provided that the establishment has supporting documentation that shows the treatment achieves a 5-log reduction for *Salmonella* and applies the treatment consistent with its critical operational parameters.

C. When establishments do not maintain clear records concerning the intended use of raw ground beef product, beef manufacturing trimmings, bench trim, or other raw ground beef components, IPP are to consider that these products are intended for use in the production of raw non-intact products. Such products are subject to VAAFM sampling and testing for STEC.

D. If a product is subject to being sampled, IPP are to sample the product even if the establishment decides to change the product's intended use (e.g., to cook all the product represented by the sample or to send the product to another establishment to cook the product after VAAFM has collected the sample). In this situation, IPP are to proceed with submitting the sample to the laboratory for analysis.

E. IPP are to use Figure 1 to determine whether the products produced by the establishment are subject to routine sampling and testing and then are to perform the "Update Profile-Raw ground beef products" and "Update Profile- Other components" as described in Chapter III.

CHAPTER III – PHIS PROFILE RESPONSIBILITIES

I. MANAGING THE PHIS PROFILE

IPP are to follow instructions in VT Directive 10010.1 Rev 4 to keep the establishment's profile updated.

CHAPTER IV - SAMPLE COLLECTION PREPARATION

I. PREPARING TO COLLECT A SAMPLE OF RAW PRODUCT FOR STEC VERIFICATION TESTING

A. Sample Request Spreadsheet

1. A sample request spreadsheet is sent to the IIC in the beginning of the year, notifying him/her of the types of scheduled samples on a monthly basis for the entire year.
2. Follow the steps below for packaging and sending the samples under seal to either the VT Department of Health Laboratory in Burlington, or to an outside laboratory.
3. If raw beef product requested for sampling is not available during the 30 day requesting window, IPP are to notify the Meat Inspection Office.

B. For samples to be tested for E. coli O157:H7 at the VDH:

1. The inspector will notify Carrie Roberts in the Meat Inspection Office a week prior to taking a sample in order to schedule pick up by Priority Express. If no Meat Inspection Office personnel are available, the inspector shall contact Priority Express to schedule a pickup for the next day. The phone number to Priority Express is 802-862-2828 option 1 for dispatch (if needed, our account number is 3786).
2. After contacting the delivery service, please leave a voice mail message or text message on Randy Quenneville, Mike Mitchell, or Katherine McNamara's phone stating that you have scheduled a sample pickup.
3. Samples will be picked up by this delivery service in the morning. The samples will need to be taken the next day, packaged and ready to go.

C. For samples of Beef Manufacturing Trimmings to be tested for E. coli O157H7 and non-O157 STEC at outside laboratories:

1. The inspector will notify Carrie Roberts in the Meat Inspection Office the week prior to taking a sample in order to schedule pick up by UPS. If Carrie Roberts is not available, please contact Stephanie Parks to generate the UPS mailing label.
2. Once Stephanie or Carrie schedules UPS, you will receive the package label via email. Print out the label to be used on the outside of the package.

A. IPP are to provide enough time for the establishment to hold the sampled lot but not enough time to alter the process. To provide establishments enough time to hold the entire sampled lot, IPP are to:

1. Be knowledgeable concerning the establishment's production practices;

2. Provide 1 day's notice if such advance notice is sufficient for the establishment to hold the sampled lot. IPP may also provide 2 days' notice, if necessary. The amount of time needed for establishment notification is not to impede VAAFM's ability to conduct verification activities that are representative of the establishment's actual production practices. If less than 1 day's advance notice would not cause a hardship for the establishment, IPP may provide less than 1 day's notice before VAAFM collects a sample for STEC testing;

3. Consider establishment requests for more than 2 days' notice before collecting the sample based on the establishment's product and process flow. In some cases, based on this

consideration, IPP may agree that more than 2 days' notice is necessary. For example, if an establishment makes case-ready product and requests that the inspector give it notice two days before the inspector is to take a sample, so that the establishment can adjust its production levels to fill its orders but still hold the sampled lot, then the inspector is to accommodate this request. If IPP have questions about an establishment's basis for requesting more notice, they are to ask the meat inspection office.

4. Inform the establishment that it is responsible for supporting its basis for defining the production lot represented by the sample (i.e., the sampled lot); and

5. Inform the establishment that it is required to hold or maintain control of the sampled lot when VAAFM collects samples for STEC until negative results become available.

6. IPP are not to wait until the end of the month to schedule the sample. Scheduling the sample early in the month will allow more time to ensure that the sample is available during the sampling window and that the lab has availability. The IIC is responsible for coordinating the sampling and assuring all samples are collected in a timely manner, and that the office is notified prior to sample collection.

B. IPP are to be aware that VAAFM does not recognize "Clean-up to clean-up" alone as a supportable basis of distinguishing one portion of production from another portion of production.

C. IPP are to be aware that factors or conditions that may determine the sampled lot include:

1. Any scientific, statistically based sampling programs for STEC that the establishment uses to distinguish between segments of production;
2. Sanitation Standard Operating Procedures (Sanitation SOPs) or any other prerequisite program used to control the spread of *E. coli* O157:H7 cross-contamination between raw beef components during production. The following may lead to the cross-contamination between raw beef components during production:
    a. Improper sanitary dressing procedures;

    b. Insanitary product contact surfaces on equipment such as machinery and employee hand tools;

    c. Improper employee hygiene;

3. Processing interventions that limit or control STEC contamination; and
4. Beef manufacturing trimmings and raw beef components or rework carried over from one production period to another.

D. If multiple lots of raw ground beef product were produced from source materials from the same production lot from a single supplier, and some of this product was found positive for STEC, IPP are to be aware that a scientific basis is necessary to justify why any raw ground product produced at the grinder from those source materials should not be considered to be adulterated.

E. If IPP have questions concerning the establishment's definition of or support for the sampled lot, they are to contact an Enforcement, Investigations, and Analysis Officer (EIAO) through their chain of command for assistance.

NOTE: When IPP are assigned to an unfamiliar establishment, they are to discuss sampling with the establishment during the entrance meeting. As part of this discussion, IPP are to determine how much notice to give the establishment before collecting a sample.

II. ORDERING SAMPLING SUPPLIES

A. Inspectors are to verify that proper sample supplies are present, and request any supplies needed from the Meat Inspection Office on an ongoing basis.
IIC is responsible for coordinating the sampling and assuring all samples are collected in a timely manner, and that the office is notified prior to sample collection

B. For ground beef samples and components other than trim, the laboratory forms (Micro 221 Rev. 5 (12/15/2016)) are pre-filled with establishment and testing information. The IPP should verify the requested test(s) on the form to ensure product samples are tested for both E. coli O157H7 and *Salmonella*. IPP should also fill out all of the sample information. If there are questions regarding the product code, or if more forms are needed, request from the Meat Inspection Office.

C. For beef manufacturing trimmings from slaughter establishments and bench trim, the lab forms will be from the South Dakota out of state laboratory, and the IPP should verify the requested tests are non-*E. coli O157H7* STEC, *E. coli O157H7*, and *Salmonella*.

III. GENERAL SAMPLING INSTRUCTION FOR ROUTINE STEC SAMPLING

A. IPP are to notify establishment management before collecting samples. IPP are to inform the establishment of the reason they are collecting the sample (e.g., routine verification testing or follow-up sampling in response to an STEC positive).

B. IPP are to use a method for randomly selecting the production lot for sampling. IPP are to randomly select a day, shift, and time within the sample month. IPP are to collect samples from all shifts the establishment operates. There needs to be an equal chance that sampling will occur during any particular shift.

C. IPP may be assigned more than one sampling task per month in an establishment that produces raw ground beef product, beef manufacturing trimmings, other raw ground beef or beef patty components, and trim or raw non-intact product from purchased product.

1. IPP are not to collect a raw ground beef sample from the same lot of source materials (i.e., beef manufacturing trimmings, bench trim, or other raw ground beef components) that other IPP have already sampled.

2. If the establishment produces 1,000 pounds of product or less on a daily basis, or only on an intermittent basis, IPP are only to collect one sample.

D. IPP are to collect fresh and not frozen product for STEC sampling. IPP are only to collect a sample of frozen product if the establishment has a critical control point (CCP) for freezing in its HACCP plan, and freezing is an active process that achieves a reduction in STEC (e.g., a spiral freezer).

E. IPP are to collect the sample after the establishment has completed production of a lot (as defined by the establishment) and applied all antimicrobial treatments to the product to be sampled.
NOTE: Application of an antimicrobial treatment (other than a treatment that achieves a full-lethality) does not exempt the product from routine sampling.

F. HPP or irradiation can be applied in a manner that achieves full-lethality or applied so that full-lethality is not achieved. As described in Chapter II, Section III. B., if the product is to receive a full-lethality at a state inspected establishment, IPP are to verify that the establishment's hazard analysis and flow chart show that the product is intended for this use, and that the establishment has controls that ensure that the product is used as intended. If the product is being sent off-site to be treated with an intervention (e.g., HPP or irradiation) that does not achieve a full-lethality, IPP are to verify that the establishment's hazard analysis and flow chart show that the product is treated with one of these interventions, the establishment has controls that ensure the intervention is applied, and the establishment does not complete pre-shipment review until these treatments have been applied. IPP are to verify, through records review, that the establishment maintains sufficient documentation to support its assertion that product receives an intervention off-site. If so, IPP are not to sample the product.

EXAMPLE: The establishment receives letters of guarantee showing that all product is treated with the intervention and maintains records documenting on-going communication with the receiving establishment to verify that all its product is being treated with the intervention.

G. IPP at the receiving establishment are to sample the product after the intervention that does not achieve a full-lethality is applied.

H. IPP are to collect a sample even if an establishment has already tested the production lot for STEC.

I. If the establishment intends to test the product for any of the adulterant STEC before completing pre-shipment review, IPP are not to wait for the establishment to receive the test results before collecting the sample. Each time IPP collect samples tested for STEC, they are to verify that establishments are holding or maintaining control of the sampled lot.

J. If an establishment does not hold or maintain control of product tested by VAAFM for STEC, IPP are to write an NR because the establishment shipped product before VAAFM found that the product was not adulterated, and because the establishment did not complete pre-shipment review following availability of all relevant test results, as required in 9 CFR 417.5(c). In this situation, IPP are to immediately contact the office.

IV. ALTERNATIVE SAMPLING PROCEDURES FOR RAW GROUND BEEF PRODUCT SAMPLING

A. General

1. Alternative sampling procedures only apply to raw ground beef product sampling. Alternative sampling procedures are different from alternative lotting described in

Section VI of this chapter. IPP are to follow the instructions below for these alternative sampling procedures when collecting a raw ground beef sample, provided that establishments meet the specific requirements applicable to each alternative sampling procedure.

2. Alternative sampling procedures include:

a. Grinding a minimum batch of product; and

b. Sampling a lot at the start of production.

NOTE: In the event of a positive result, IPP are to be aware that VAAFM considers all same source materials used to produce the positive raw ground beef product to be positive unless the establishment has a scientific basis to distinguish production lots using same source materials (i.e., robust sampling of source materials or finished product or the application of a validated antimicrobial intervention to source materials or finished product according to the establishment's supporting documentation).

B. Grinding a Minimum Batch of Product**.** An establishment may request that VAAFM sample product from a minimum batch of product that represents the entire lot on a smaller grinder.

1. In this case, IPP are to verify that:
   a. The establishment has written procedures to grind a minimum batch of product that represents the establishment's production process in a smaller, off-line grinder;
   b. The establishment has supporting documentation that describes how the minimum batch is representative of the establishment's production process. As part of the verification that the minimum batch represents the establishment's normal process, IPP are to ensure that the documentation includes an appropriate proportion of all types and suppliers of trim used to produce the larger production lot; and
   c. The minimum batch is not less than 50 pounds.
2. If the establishment meets the criteria in B. 1 above, IPP are to sample this minimum batch of product after randomly selecting the day, shift, and time and notifying the establishment as set out in Sections I and IV of this chapter. If the establishment does not meet the criteria, IPP are to collect the sample as described in Ch. V.

C. Sampling a Lot at the Start of Production. An establishment may request that VAAFM sample a lot of raw ground beef product at the start of production.

1. In this case, IPP are to verify that the establishment has production schedules that define the specific components used at specific production times.

2. If the establishment does operate in accordance with schedules of this type, IPP are to:

a. Randomly select a production date and time within the sample collection month;

b. Select a time of production for sampling that is after the beginning of operations. If the establishment has documentation showing that it is scheduled to grind a specific lot of product at a specific production time, IPP are to allow the establishment to grind that lot of product at the beginning of operations on the day that IPP schedules a sampling task; and

c. Verify that the establishment is not treating the source materials of the raw ground product that VAAFM samples differently from other source materials used for grinding. For example, IPP are to verify that the establishment is not using interventions on the source material that it does not normally use on the ground product VAAFM will sample.

3. If an establishment requests that VAAFM sample raw ground beef product at the start of production, and it meets all these criteria, IPP are to collect samples at the start of production. If the establishment does not meet the criteria, IPP are to collect the sample as described in Ch. V.

IV. ALTERNATIVE LOTTING FOR RAW GROUND BEEF PRODUCT, BEEF MANUFACTURING TRIMMINGS, OTHER RAW GROUND BEEF COMPONENTS, AND BENCH TRIM SAMPLING

A. An establishment may request to reduce its lot size to one combo bin or some other unit (e.g., box) for samples of raw ground beef, beef manufacturing trimmings, other raw ground beef components, and bench trim on the day that VAAFM collects samples.

B. In this case, IPP are to verify that the establishment:

1. Has a validated intervention for STEC at a CCP in the HACCP plan under which the beef manufacturing trimmings or other raw ground beef components are produced or requires its suppliers to have a CCP where a validated intervention is applied to the source materials used to manufacture the raw ground beef product or bench trim; and

2. Samples and tests every production lot for STEC and generally collects its samples of raw ground beef, beef manufacturing trimmings, other raw ground beef components, or bench trim across multiple combo bins or other sample units.

C. If an establishment meets the criteria in B. above, and reduces its lot size of ground product or bench trim from source materials, beef manufacturing trimmings, or other components to a single combo bin or sample unit when VAAFM samples the product, IPP are to collect a sample from the single combo bin or sample unit. If the establishment does not meet the criteria, IPP are to collect the sample as described in Ch. V.

VII. GATHERING SUPPLIER INFORMATION

A. IPP are to gather information about the source materials and suppliers at the time they collect a routine raw ground beef and bench trim sample, as well as when they do follow–up sampling to these programs. See Attachment 2 for the supplier and source material information they are to gather at the time they collect raw ground beef and bench trim samples. This information

enables VAAFM to trace the raw material back to the original slaughter establishment. IPP can keep the actual label from empty packages. Establishment management can also provide information about the source materials.

B. See VT Notice 13-A for instructions on how to document in PHIS

CHAPTER V – SAMPLE COLLECTION PROCEDURES

I. GENERAL

A. The establishment may be eligible for more than one sampling program. IPP are to sample beef components, beef manufacturing trimmings, and bench trim separately following the instructions provided in this Chapter. When the establishment produces multiple types of trim or components, IPP are to randomly select beef manufacturing trimmings, bench trim, and beef components and collect samples independently. For a given sampling event, IPP are to collect only one type of trim or component type, whenever possible. The intent is that, through random selection, all eligible products the establishment produces that are subject to sampling will likely be selected over time.

B. IPP are to collect samples of a lot according to the establishment's lotting practices.

C. IPP are to use aseptic technique, including proper gloving technique, when collecting samples. See Attachment 1

D. STEC Sampling of Domestic Raw Beef Products Video training is available online. See Attachment 5 for information on how to get credit for completing the optional training.

E. Attachments containing step-by-step sample collection procedures by sampling type are available. Attachment 3 provides sample collection procedures for beef manufacturing trimmings and bench trim. Attachment 4 provides sample collection procedures for other raw ground beef components. Attachment 2 provides sample collection procedures for raw ground beef product.

II. FINAL PACKAGING

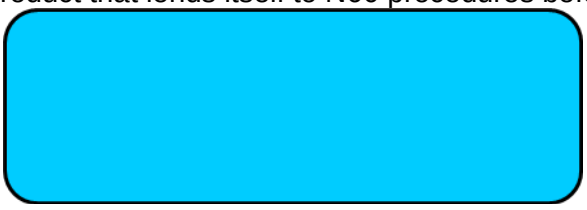
A. IPP are to collect raw ground beef products in their final package whenever possible. IPP are to collect the appropriate number of packaged products so that the sample equals **two pounds**.

B. IPP are to place the product collected in its final packaging in the larger, non-sterile bag provided with the sampling supplies. IPP are not to use the Whirl-pak® bags when collecting products in its final packaging.

III. N60 SAMPLING METHOD

A. N60 sampling is the sample collection method IPP are to use when collecting samples of beef manufacturing trimmings and bench trim, provided the establishment produces beef manufacturing trimmings and bench trim in amounts that are large enough to be sampled using the N60 method. IPP assigned to establishments that produce beef manufacturing trimmings and bench trim of sufficient size to be sampled using the N60 method and trim too small to be sampled using the N60 method are to collect samples from the product that lends itself to N60

procedures. If the establishment commingles both types of trim, whenever possible, IPP are to collect samples from the product that lends itself to N60 procedures before commingling.



(approximately 1 inch X 3 inches)

Example of the dimensions a single sample slice

NOTE: If the establishment only produces beef manufacturing trimmings and bench trim that is too small to be sampled using the N60 method, IPP are to collect a sample by taking aseptic grab samples (see Section IV in this chapter).

B. IPP are to not to use the N60 method when collecting other raw ground beef component samples. IPP are to collect other raw ground beef component samples by taking aseptic grab samples (see Section IV in this chapter).

C. N60 sampling involves collecting 60 thin slices from the external surface of beef tissues. Each sample slice should be about 3 inches long by 1 inch wide and 1/8th inch thick, as shown above. It is important to collect thin slices because the surface of the beef carcass can be contaminated through improper sanitary dressing procedures. IPP are to collect only one sample slice from each of the 60 individual pieces of trim. IPP are not to take multiple samples from a single piece of beef manufacturing trimmings unless the production lot consists of less than 60 individual pieces. Collecting thin slices from the external surface maximizes the amount of surface area sampled, which increases the likelihood of finding pathogens if they are present.

D. IPP are to use the 3 Whirl-Pak bags when collecting samples using N60 procedures. IPP are to place 30 pieces in each of the two Whirl-Pak bags.

NOTE: When cut to the correct size, 30 sample slices should fill one Whirl-Pak bag to the fill line. In the third Whirl-Pak bag, IPP are to aseptically collect samples of trim from the same production lot by using a grab sample technique. For larger trim pieces, IPP are to cut the trim piece so that it fits in the Whirl-Pak bag with at least 2-3 inches of space at the bag.

E. IPP are to randomly select one production lot according to the establishment's lotting practices with each lot having an equal chance of being selected regardless of product location.

1. If an establishment's specific production lot is greater than 5 containers, IPP are to select randomly 5 containers for sampling with each container having an equal chance of being selected; and

2. If the establishment's specific production is 5 or less containers, IPP are to refer to Table 4 to determine the number of sample pieces to collect from each container.

TABLE 4: Number of Sample Pieces to Collect Per Container

# of containers in each specific lot	*# of sample pieces to select from* each *container*
5	12 pieces
4	15 pieces
3	20 pieces

IV. ASEPTIC GRAB SAMPLING

A. IPP are to aseptically collect grab samples and are not to use the N60 sample method when collecting other raw ground beef component samples.

B. IPP are to aseptically collect grab samples when raw ground beef product is not available in its final packaging, or the package is too large.

C. For aseptic grab samples, IPP are to collect a sufficient quantity of product to fill each of the three Whirl-Pak bags to the fill-line. For larger components, such as hearts, IPP are to collect one or more pieces or enough to fill each of the 3 Whirl-Pak® bags above the fill line but leaving at least 2-3 inches of space at the top of the bag when collecting samples.

V. **PHIS QUESTIONS RELATED TO SAMPLE MATERIAL**

A. For each sample of beef manufacturing trimmings collected in the sampling program, IPP are to answer the following questions and copy and paste them into the Findings tab in the appropriate PHIS task, as indicated in See VT Notice 13-A for instructions on how to document in PHIS.

See also Attachment 7

B. Following some of the answer choices is guidance to assist IPP with answer selection.

1. Does the sampled lot contain beef manufacturing trimmings from cattle slaughtered only on-site?

    a. Yes

    b. No

2. Does the sampled lot contain only beef manufacturing trimmings and no other components?

    a. Yes: IPP are to select ‘Yes’ when they have verified that the entire sampled lot is composed only of beef manufacturing trimmings and does not contain any amount of other components or other material.

    b. No: IPP are to select ‘No’ when the sampled lot contains any amount of material other than beef manufacturing trimmings.

C. If IPP have concerns that an establishment is changing its lotting practices or other normal operational practices (including lot composition) to limit VAAFM from testing beef manufacturing

trimmings samples for the relevant non-O157 STECs, IPP are to consult their supervisory chain of command for further instructions

VI. PACKING AND SHIPPING THE SAMPLE

Pre-chill the shipping container supplied by the VT Meat Inspection Office. Keep samples refrigerated at all times. Do not freeze. Use only frozen gel pack in shipping containers. Do not use ice or dry ice.

IPP are to safeguard the integrity of samples during submission according to VT Directive 7355.1, Use of Sample Seals for Laboratory Samples and Other Applications:
Place a Vermont seal barcode on each sample taken (i.e. on the whirlpak bag or on the product sample package) and on the corresponding laboratory form for that sample. Put the sample package or whirlpack bag(s) you are submitting in a sealable ziplock bag to prevent leakage. Place the long thin Vermont Seal over the opening of the bag.

Place samples in the pre-chilled shipper. The laboratory form is placed in a separate plastic bag, and put in the shipper as well. Place the cardboard on top of the sample, and then add the cold gel pack on top. Replace the white Styrofoam top to the insulated shipping container, and close the outside box using tape.

Place the large VT seal over the box closure.

Samples will be carried to the lab via Priority Express. Samples will be kept refrigerated using reusable ice packs in the shipping container. IPP are to safeguard the security of samples when preparing, storing, packaging, and submitting samples for testing. The samples will not be shipped on Thursdays, Fridays or the day before a state holiday.

VII. ACCESSING TEST RESULTS

A. The chief and head of service are notified of results by the VDH laboratory via email. Hard copies of each of the lab results are sent to the VT MPI Program Office, and each is reviewed by the Head of Service or The Chief of Inspection. A master list of all samples, is kept and updated with each sample result received. Reasons for discard/invalid results are listed on the individual laboratory sample sheets.

B. The chief and head of service are notified of results by out of state laboratories supplying us with testing services.

C. After receiving the STEC test results, IPP are to advise an establishment that is holding product that it does not need to continue to hold that product if it has tested negative for STEC. IPP are to be aware that establishments are not required to hold product when only *Salmonella* results are pending. If IPP receive *Salmonella* results before the *E. coli* O157:H7 results, they are to wait to notify the establishment until after receiving the STEC results.

CHAPTER VI – VAAFM ACTIONS IN RESPONSE TO VAAFM, FEDERAL, OR STATE ENTITY STEC TEST RESULTS

I. NEGATIVE TEST RESULTS

IPP are to immediately notify the establishment of negative test results, so that the establishment can release product.

II. POSITIVE TEST RESULTS

A. If a sample is presumptive positive, the VT Dept. of Health notifies the meat inspection office verbally and in writing of a presumptive positive. The official result is verbally communicated to the office, and also mailed to the office via the State of VT mail system.

B. The same notification will apply to out-of-state laboratories supplying us with testing services.

C. Presumptive and Confirmed Positives:

1. Samples are initially analyzed with a PCR protocol for detecting E. coli O157H7.
2. For samples run by VDH, a Presumptive Positive is a sample that is PCR positive, but still needs to be cultured.
3. A Confirmed Positive is a biochemically-identified *E. coli* isolate that is serologically or genetically determined to be O157, O26, O45, O103, O111, O121, or O145, and that meets at least one of the following criteria:
    a. positive for Shiga toxin (ST) production
    b. positive for the Shiga toxin gene (stx)
    c. genetically determined to be "H7"

Typically, the *STEC* negative test results become available in 1-2 days, and confirmatory testing becomes available four to five days after the laboratory receives the sample.

D. Plan of Action for positive result

If the results are **presumptive positive**, the VT MPI Program will confirm the collection of the following information regarding the suppliers of the source materials used in the production of the product (9 CFR 320.1):

1. name of the supplying establishment, point of contact (name, title, e-mail address, and fax number), and phone number of supplying establishment;
2. supplier lot number; and
3. production date, name of supplied material, and any additional information to clearly identify the material used of the management of the supplying establishment.
4. IPP are to identify specifically the type of source materials the establishment used in producing the ground beef (e.g., beef trimmings, subprimal cuts, beef hearts, veal trimming, and head or cheek meat).

E. Inspection program personnel make note of any information that the establishment is unable to provide.

IV. Office RESPONSIBILITIES IN RESPONSE TO A CONFIRMED POSITIVE TEST RESULT

A. General

1. IPP will only be instructed to collect follow-up samples from the establishment that produced the confirmed positive product and the originating slaughter establishments (see Chapter VII).

B. In response to a confirmed positive sample result, the Office is to:

1. Direct IPP at supplying establishments to perform tasks:
   a. The office is to direct the IPP at all establishments that supplied product represented by the positive sample, including the originating slaughter establishments, to perform directed HACCP and Sanitation SOP verification tasks per Sections V and VI of this chapter.
   b. The office is to direct the IPP at originating slaughter establishments to perform a directed Sanitary Dressing task.

2. Schedule a for-cause Public Health Risk Evaluation (PHRE) and after the completion of the PHRE take appropriate enforcement actions, if warranted, or schedule a for-cause Food Safety Assessment (FSA), as described in FSIS Directive 5100.4, *Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology*.

C. The Office is to take the appropriate enforcement actions (e.g., NOIE, withhold or suspend inspection, reinstate a suspension), if warranted, based on EIAO or IPP findings.
D. Below are factors the office is to consider when making a determination about whether to stop collecting follow-up samples and to take a suspension or withholding action:
   1. the establishment is failing to implement proposed corrective actions;
   2. the establishment's corrective actions that the establishment is implementing are ineffective;
   3. the establishment has recurring sanitary dressing noncompliances that render its corrective actions ineffective (see VT/FSIS Directive 6410.1); or
   4. the establishment does not have support for decisions made in its HACCP plan or hazard analysis (see current FSIS Directive 5000.1).

V. IPP RESPONSIBILITIES AT THE ESTABLISHMENT WITH A CONFIRMED POSITIVE TEST RESULT

A. In the event of a confirmed positive result in raw ground beef product or beef trim or other components intended for use in raw non-intact product, the sampled lot is adulterated.

B. Inspection personnel and the VT MPI Office work together to determine the necessity of product retention, detention, or recall. The Technical Services Center (TSC) and OPHS may also serve as technical resources to assist in the decision making process. The VT MPI Office will contact inspection program personnel and program investigators as necessary (see FSIS Directive 8080.1, Revision 7).

B. IPP are to perform a directed HACCP Verification task for the specific production lot that tested positive and document noncompliance, where appropriate as described in VT Directive 10,010.2, to

verify that the establishment meets the applicable regulatory requirements at all CCPs in the HACCP plan (e.g., monitoring, verification, recordkeeping, corrective actions, and reassessment) for the implicated production lots for the that tested positive for *E. coli* O157:H7 or non-O157 STEC and verify that the establishment implements corrective actions that meet regulatory requirements.

C. IPP are to perform a directed Sanitation SOP task and are to verify that the establishment is properly implementing its Sanitation SOP as set out in VT Directive 5000.1.

D. IPP are to perform a directed Beef Sanitary Dressing task as described in FSIS Directive 6410.1, *Verifying Sanitary Dressing and Process Control Procedures by Off-Line Inspection Program Personnel (IPP) in Slaughter Operations of Cattle of Any Age*, if the positive sample result was from product from the establishment's own slaughter operation.

E. IPP are to collect follow-up samples as described in Chapter VII.

F. If disposition of the positive product will be delayed, inspection program personnel should work with the VT MPI Office to determine how to work with the establishment to ensure proper and timely disposal of the product.

VI. IPP RESPONSIBILITIES ASSIGNED TO ESTABLISHMENTS THAT SUPPLIED THE SOURCE MATERIALS USED TO PRODUCE THE POSITIVE PRODUCT

A. IPP assigned to supplying slaughter and further processing establishments are to:

1. Perform a directed HACCP verification task as described in FSIS Directive 10,010.2, for the specific production lot of source materials used to produce the product that tested positive; and

2. Perform a directed Sanitation SOP task of reviewing records for the day or days that the source materials used to produce the product that tested positive.

B. IPP assigned to supplying slaughter establishments are to:

1. Perform a directed Beef Sanitary dressing task; and
2. Conduct follow-up sampling as described in Chapter VII.

C. Sample discard: If the Laboratory discards a sample submitted for STEC testing, IPP are to notify establishment management so that product may be released. IPP are to take appropriate action, based on the reason for the sample discard when applicable. IPP are to review the reason for sample discard and make the necessary adjustments in how the samples are collected, sealed, and shipped to ensure that the laboratory does not discard future samples because of improper handling or packaging.

NOTE: There may be reasons for sample discards (e.g., courier issues, lab issues) that are beyond IPP control.

CHAPTER VII –FOLLOW-UP SAMPLING PROCEDURES

I. GENERAL

A. IPP are to collect follow-up samples in response to VAAFM positives as soon as possible after the positive results were obtained, unless the establishment stops producing any raw beef product intended

for raw non-intact use. The purpose of follow-up sampling is to determine whether the establishment's process is effectively addressing STEC.

B. IPP are to collect follow-up samples from the same type of product that tested positive, if available. If the establishment is not producing the product requested, IPP are to collect follow-up samples from beef manufacturing trimmings if the establishment is producing them.

C. In the event that the establishment does not produce the product that tested positive or beef manufacturing trimmings, IPP are to collect follow-up samples from other raw ground beef components or bench trim, if available.

D. IPP are not to wait until the establishment takes corrective actions or has confidence that its corrective actions are effective to collect follow-up samples.

E. When positive product is derived from cattle not slaughtered at the establishment-

1. Inspection program personnel are to begin collecting samples from lots produced after the positive product as soon as possible following receipt of the multiple follow-up sample requests, even if the establishment is still completing corrective actions required under 9 CFR 417.3. Although inspection program personnel are not to wait for the establishment to complete corrective actions, they are to collect follow-up samples when the establishment has resumed normal production.
2. Inspection program personnel are to collect 8 samples for low volume establishments (establishments that produce less than 1,000 pounds per day of product in question) as per FSIS Notice 79-08:

    1. a maximum of 2 follow-up samples per shift per day from different lots (or up to 4 samples per day at a 2-shift establishment), unless the establishment cannot continue to operate under that sampling frequency (e.g., because the establishment cannot fill orders and hold all sampled product), or the inspection program personnel's workload cannot accommodate that sampling frequency; and

    2. a minimum of 3 follow-up samples per week, unless the establishment produces the product in question less than three times per week, the establishment cannot continue to operate under that sampling frequency, or the inspection program employee's workload cannot accommodate that sampling frequency.

G. VAAFM also schedules follow-up sampling sets at supplying slaughter establishments in response to a positive from raw ground beef sample and a bench trim positive.

H. VAAFM may also schedule a follow-up sampling set outside these follow-up sampling projects, e.g., in response to an outbreak or recall.

I. Each positive result in a follow-up sampling set triggers another follow-up sampling set. IPP are to continue to collect samples until enough follow-up samples have been collected to reach the desired number of consecutive negatives to complete the follow-up sampling sets.

II. FOLLOW-UP SAMPLING AT SUPPLIERS

A. If the originating slaughter establishments supplied more than one type of source material used in the positive ground beef or bench trim sample, each type of source material should be sampled.

B. If it is determined that an originating slaughter establishment was the only supplier, or that any of the originating slaughter establishments were suppliers that had previously had positive STEC tests in the last 120 days of the current raw ground product or bench trim positive result, they will be assigned 16 (or 8 if the establishment produces less than 1,000 pounds per day of the product that tested positive) follow-up sampling tasks for the originating slaughter establishments. The follow-up samples are identified for each component used in the positive raw ground beef or bench trim product.

1. If a supplier is not a sole supplier, they will be assigned a single follow-up sample for each component used in the positive raw ground beef or bench trim product.

3. In combination slaughter/processing establishments, if ground product is found positive by VT regulatory testing, and the establishment produced the source materials used to produce the ground product, IPP are to collect either 8 or 16 samples, based on establishment size, of the type of source materials used in the positive raw ground beef product. IPP are not to collect follow-up samples of ground product.

NOTE: Follow-up samples of raw ground beef product are to be collected from the grinders that used purchased source materials (see Section I.F.1. of this chapter).

III. SPECIAL INSTRUCTIONS FOR FOLLOW-UP SAMPLING (MT52) OF INTACT BEEF COMPONENTS THAT WERE NOT INTENDED FOR USE IN RAW NON-INTACT PRODUCT

A. If intact product was used as a component in raw ground beef product or was sampled as bench trim that VAAFM finds positive for *E. coli* O157:H7, IPP are to select a carcass (rather than the component of the carcass) at the originating slaughter establishment for follow-up sampling under the following conditions:

1. HACCP plan records and purchase specification records for product produced at the originating slaughter establishment show that the intact product was not intended for grinding or non-intact product, and that the establishment informed purchasers that the product was not intended for grinding; and

3. The establishment derived intact product from the carcass in a manner to minimize commingling with other product, and the establishment packaged the product separately from other product without commingling (e.g., boneless chucks were placed on a conveyor belt and were then off-loaded for packaging without being commingled with other product). IPP can verify that the establishment handled the product this way through records review and direct observation.

B. IPP are to verify that that the conditions in A. above are met. If the conditions in A. above are met, IPP are to collect the samples at the originating slaughter establishment from one or more carcasses hanging in the cooler before fabrication, according to the establishment's lotting practices.

1. IPP are not to wait until the establishment breaks the carcass down into primal and subprimal cuts to collect follow-up samples. IPP should take the slices from the carcass while the carcass is hanging in the cooler before fabrication.

2. IPP are to use the N60 method to collect slices from the carcass surface from the same part of the carcass used to produce the raw ground beef product or bench trim, if known.

a. If the location on the carcass is not known, then IPP are to sample:

i. Inside round;

ii. Outside round;

iii. Navel plate;

iv. Brisket; and

v. Foreshank

b. If the slaughter establishment designates more than 1 carcass as a lot, then IPP are to collect samples from more than 1 carcass as follows:

TABLE 5: Number of Sample Pieces to Collect Per Carcass

# of carcasses in each specific lot	# of sample pieces to collect from each carcass
5 or more	12 pieces
4	15 pieces
3	20 pieces
2	30 pieces
1	60 pieces

NOTE: If the follow-up sample collected is positive, only the sampled carcass is implicated because *E. coli* O157:H7 contamination is generally point-source contamination that occurs sporadically as a consequence of handling during hide removal and dressing of the carcass. The establishment may decide to destroy the implicated carcass or to use it to produce products that will be processed to destroy the pathogen (e.g., by cooking or irradiation).
Because establishments remove the head and cheek meat from the skull during the slaughter process and process it separately from the rest of the carcass, head or cheek meat will not be implicated by the positive result.

If the supplier was a federal establishment, the information will be forwarded to the originating District Office.

Attachment 1

ASEPTIC SAMPLING TECHNIQUES

A. Preparing For Sampling

1. Extraneous organisms from the environment, hands, clothing, sample containers, and sampling devices may lead to erroneous analytical results. Stringent requirements for microbiological analysis are necessary; therefore, use of aseptic sampling techniques and of clean, sanitized equipment is of utmost importance.

2. If an area is designated for preparing and gathering sampling supplies, IPP should use it. IPP may choose to use a stainless steel, wheeled cart, if available, when carrying out the actual sample collection procedure. IPP may choose to use a small tote or caddy to carry items to the sampling location.

3. IPP are to wear sterile gloves while collecting samples. The only items that should contact the external surface of the sterile glove on the sampling hand are the sample being collected and the sterile sampling equipment. The outside surfaces of the sample container are not sterile.

B. Putting On The Gloves

IPP are to first wash and sanitize their hands to the mid-forearm. IPP are to dry their hands using disposable paper towels. IPP are to follow the procedure for putting on sterile gloves.

1. IPP are to position the glove package so that the letters L and R are facing them (L=left, R=right)

2. When the package is opened, the gloves are folded, forming a cuff on the sleeve, and lying palm up. IPP are to leave the gloves in the package until they put on the gloves.

3. IPP are to hold one glove open by the inside cuff, insert a hand into the glove, palm-side up, and remove the glove from the package.

4. IPP are to pull the glove completely on with the ungloved hand, touching only the inside cuff, and pull the cuff up without touching the outside surface of the glove with the ungloved hand.

5. IPP are to repeat this procedure with the other glove, with one key exception. IPP are not to handle the second glove inside the cuff because hands are not sterile. Therefore, IPP are to place the ungloved hand, palm up, into the second glove.

6. IPP are to insert the fingers of the gloved hand into the fold of the second cuff and ease the second cuff onto the hand and handle the second glove from the outside to adjust the cuff on the wrist.

7. Once both gloves are on, IPP can touch the outside of a glove with the other gloved hand to adjust the fit.

NOTE: If at any time IPP are concerned that they may have contaminated a glove, they are to discard it and repeat this procedure for putting on sterile gloves.

Attachment 2

Collecting A Ground Beef Sample

NOTE: IPP are to collect samples from product that contains a mixture of ground beef and non-beef species, unless the establishment labels the product in a manner to show that ground beef is not the predominant species in the product.

Sampling supplies for raw ground beef sampling

3 - Sterile Fill- Line Closure Whirl-Pak® Bags
1 - 13x18" Zipper Lock Bag
1 - pair Sterile Gloves
1 - VT Form 7355-2A/AB (sample seal set)
1 - 6" x 12" plastic sleeve
1 - Shipping Container
1 - Gel Coolant Pak
1 - Cardboard Separator
1 - Absorbent Pad

Upon receipt of the sampling supplies:
1. Verify receipt of all supplies needed to perform the sample collection.
2. Remove gel coolant packs from the shipping container and place them in the freezer at least 24 hours prior to s
collection. Pre-chill the shipping container.

On the day of sample collection:

1. Find a suitable workstation near the production area to place your equipment.

2. Clean and sanitize your workstation and caddy and allow them to air dry. If a sanitizable surface is not available near the area where you will perform the sample collection, use the sterile plastic drape to create a work surface for your sanitized sampling equipment.

A. Collecting a Raw Ground Beef Sample in Its Final Package

1. When collecting ground beef in its final packaging, collect the appropriate number of packaged products so that the sample equals two pounds.
For example, if raw ground beef is packaged in 1 lb. chubs, then collect two – 1 lb. chubs.
2. Place the product collected in its final packaging in the larger, non-sterile bag with the sampling supplies. Do not use the Whirl-pak® bags.

3. Whenever possible, IPP are to take samples that are in their final packages. If ground product in final packages is not available for sampling (e.g., if the ground product final package is too large) or for any reason IPP are not able to collect a 2-pound package of finished product, IPP are to collect the 2-pound grab sample aseptically and use the sterile gusseted whirlpak bags.

B. Collecting a Raw Ground Beef Grab Sample

NOTE: Use this method to collect raw ground beef product samples if it is not available in its final packaging or the package is too large.

1. Wash and dry your hands.
2. Open the sterile Whirl-Pak® bags. To open, remove the tear strip from the top, grasp the two small white tabs and pull apart. Do not touch the interior surface of the bag.
3. Position the Whirl-Pak® bag close to area where you will take the samples. The bag has a gusseted bottom so, once product is added, it will stand upright.
4. Put on the sterile gloves.
5. Aseptically collect grab samples of raw ground beef.
6. Collect a sufficient quantity of raw ground beef to fill each of the three Whirl-Pak® bags to the fill-line.

Do not under-fill or overfill the bag.

7. Once sample collection is complete, carefully expel excess air from each Whirl-Pak® sample bag, tightly fold over the top at least four times and then fold over the side tabs to secure the folds in place. Do not tie the ends.

Attachment 3

Beef Manufacturing Trimmings / Bench Trim

Sample Collection Using N60 Method and Grab Sample Method

Upon receipt of the sampling supplies:

1. Verify receipt of all supplies needed to perform the sample collection.
2. Remove gel coolant packs from the shipping container and place them in the freezer at least 24 hours prior to sample collection. Pre-chill the shipping container.

On the day of sample collection:

1. Find a suitable workstation near the production area to place your equipment.

2. Clean and sanitize your workstation and caddy and allow them to air dry.

3. Sanitize the knife, steel, and hook. Allow them to air dry.

NOTE: Use the same sanitizing solution used by the establishment, if one is used, according to label directions. If the establishment uses only hot water, then use hot water only to sanitize your sampling equipment. If no method of sanitizing used by the establishment, then use the sanitizing solution available from the office.

4. Wash and dry your hands.

5. Open the sterile Whirl-Pak® bags. To open, remove the tear strip from the top, grasp the two small white tabs and pull apart. Do not touch the interior surface of the bag.

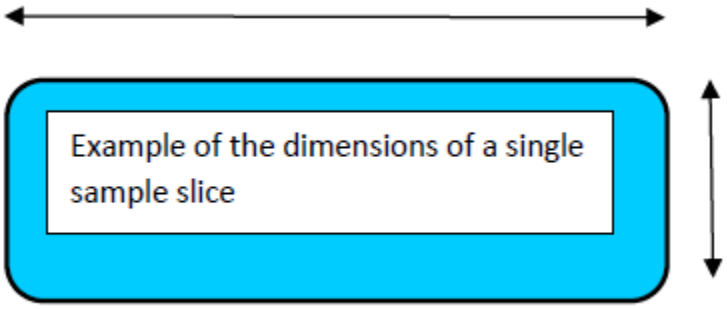
6. Position the Whirl-Pak® bag close to area where you will take the samples. The bag has a gusseted bottom so, once product is added, it will stand upright.

7. Put the mesh glove on your non-knife hand and put on the sterile gloves.
8. Aseptically collect the trimmings from one production lot. Use the sanitized hook to position and anchor a piece of meat at the top of the container.

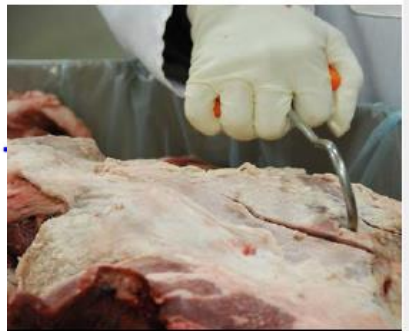
For larger trim, you may want to use a curved boning knife and short boning hook instead of the standard hook and standard boning knife.

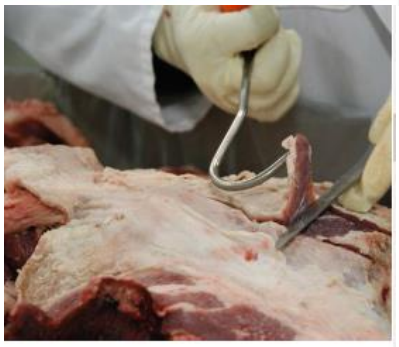
Collect samples from the original external surface of the carcass.

9. Use the N60 method. The N60 method involves 60 thin slices from the external surface of beef tissues. Each sample slice should be about 3 inches long by 1 inch wide and 1/8th inch thick. It is important to collect thin slices because the surface of the beef carcass can be contaminated through improper sanitary dressing procedures. To make cutting easier, score the surface of the meat in two parallel cuts. These cuts should be 1 inch apart and 3 to 4 inches long. This can make it easier to cut the sample slice to the right size.



10. Cut off a slice of the surface that is approximately
1 inch wide by 3 inches long and 1/8th inch thick. Remember to focus on thin slices from the external surface tissue. Collect only one sample slice from each of the 60 individual pieces of trim. Do not collect multiple sample slices from a single piece of trim unless the lot to be production lot consists of less than 60 individual trim pieces.





NOTE: It is important to keep the strips very thin and that you submit as much external surface as possible. Take care to ensure the samples contain some meat because if the entire sample is fat, the fat can interfere with the sample analysis

11. Place each slice in one of the sterile Whirl-Pak® bags. Continue this process until you have collected 30 pieces in one Whirl-Pak bag.

12. Repeat steps 9 through 11 until you have collected two Whirl-Pak® bags each containing 30 slices.

NOTE: When cut to the correct size, 30 sample slices should fill one Whirl-Pak® bags to the fill line.

Photo showing the correct sample size for each N60 piece when compared next to the template

13. In the third sterile Whirl-Pak® bag, aseptically collect samples of trimmings from the same production lot by using a grab sample technique. It is not necessary to count the number of pieces or to cut the pieces to a certain dimension. Collect pieces with as much external surface as possible.

For larger trim pieces, such as chucks, cut the large trim piece so that it fits in the sample bag but make sure you leave at least 2 - 3 inches of space at the top of the bag and expel as much air out of the bag before closing it.

14. Once sample collection is complete, carefully expel the top at least four times and

then fold over the side tabs to secure the folds in place. Do not tie the ends.

15. If the available bench trim is too small for N60 sampling, aseptically collect grab samples and fill each of the 3 Whirl-Pak® bags up to the fill line. Collect pieces with as much external surface as possible.

16. Follow the instructions in Step 14 for closing and securing the Whirl-Pak® bags.

Collecting Bench Trim Product from Cattle not Slaughtered On-Site

- Bench trim is defined as beef manufacturing trimmings derived from cattle not slaughtered on site at the establishment. Such trim may include secondary trimming of primals and subprimals resulting in small or large pieces, or any other cuts designated for non-intact use. Such trim would not already be sampled under the current routine trim testing program or the routine testing program for other raw ground beef or patty components.
- Establishments that produce bench trim derived from cattle not slaughtered on-site are subject to sampling under this program. Therefore, the sampling frame will include establishments that receive whole or half carcasses, primals, and boneless boxed beef that they use to produce bench trim.
- At establishments that produce bench trim derived from cattle not slaughtered on-site intended for use in raw ground beef product, IPP will sample the bench trim as follows:
    1. If the establishment produces trim derived from primals and subprimals resulting in large pieces, IPP are to sample the product using the N60 sampling above;
    2. If the establishment produces trim derived from primals and subprimals resulting in trim too small to be sampled using the N60 sampling procedure or produces trim derived from steaks, roasts or other cuts designated for non-intact use, IPP are to collect enough pieces to equal 2 pounds of product for sampling using the grab sample technique above.
    3. If the establishment produces both types of trim as described above, IPP are to sample only the product that can be sampled using the N60 sampling procedure.

4. If the establishment commingles both types of trim, IPP are to collect samples from the product that lends itself to N60 procedures.

- In cases in which the establishment's records and HACCP documents are unclear about the intended use of the bench trim, IPP are to consider the product as intended for use in raw ground beef products and sample the product.

Attachment 4

Raw Ground Beef Components other than Beef Manufacturing Trimmings (heart meat, weasand, head meat, cheek meat)

- When IPP receive a sampling request letter requesting raw beef components other than trim, IPP choose the products produced at the slaughter establishment by following the priority list below. For example, if the establishment produces product from AMR systems (first on the priority list below) on the day of collection, IPP are to take a sample of it; if not, they are to collect product from Low Temperature Rendered Beef (LTRB) (second on the priority list) if it is available, and move down the list until there is an available product.

The priority list is:

a. Product from AMR Systems (none currently in Vermont)
b. Low Temperature Rendered LTRB (none currently in Vermont)
c. Partially Defatted Beef Fatty Tissue (none currently in Vermont)
d. Partially Defatted Chopped Beef (PDCB) (none currently in Vermont)
e. Weasand Meat
f. Head Meat
g. Cheek Meat
h. Heart Meat

Upon receipt of the sampling supplies:

1. Verify receipt of all supplies needed to perform the sample collection.
2. Remove gel coolant packs from the shipping container and place them in the freezer at least 24 hours p
sample collection. Pre-chill the shipping container.

On the day of sample collection:

1. Find a suitable workstation near the production area to place your equipment.

2. Clean and sanitize your workstation and caddy and allow them to air dry.

3. Wash and dry your hands.

4. Open the sterile Whirl-Pak® bags. To open, remove the tear strip from the top, grasp the two small white tabs and pull apart. Do not touch the interior surface of the bag.

5. Position the Whirl-Pak® bag close to area where you will take the samples. The bag has a gusseted bottom so, once product is added, it will stand upright.

6. Put the mesh glove on your non-knife hand and put on the sterile gloves.
NOTE: It is not necessary to put on a mesh glove prior to gloving if the sample collection will not require any cutting of beef components to facilitate their placement in the sample bags.

7. Randomly select one component type the establishment produces. Do not include multiple component types in a sample, whenever possible.

8. When sampling raw ground beef components other than trim, you may need to cut these components (e.g., head meat, cheek meat, weasand, or heart) into smaller pieces to fit into the Whirl-Pak® bags. You will not use the N60 sampling method to collect other component samples.

   a. For larger components, such as hearts, collect one or more pieces or enough to fill each of the 3 Whirl-Pak® bags above the fill line but leaving at least 2-3 inches of space at the top of the bag.

b. When sampling smaller component types (such as AMR product or low temperature rendered products), aseptically collect grab samples and fill each of the 3 Whirl-Pak® bags up to the fill line.

Establishments Producing Primals and Subprimals

- Establishments may produce primals or subprimals (or, if primals are further trimmed or processed into consumer-ready steak and roast products) that are used in both intact and non-intact product (e.g., tenderized steaks and ground beef). However, the establishment may have no way of consistently knowing the final use or user of the product. Therefore, the establishment that produces primals or subprimals may not be able to identify whether the final end product will be intact or non-intact product. In this case, IPP are to

collect samples of beef trimmings when the slaughter establishment produces beef trimmings destined for use in raw ground beef or other non-intact product since the intended use of the product is unclear.

- Typically, primals and subprimals are not adulterated if contaminated with *E.coli* O157:H7 because they are intact products for which cooking by the consumer results in a safe product. If slaughter suppliers that produce primals or subprimals supplied primals or subprimals that were used in the production of ground beef product that FSIS or another Federal or State entity found positive for *E. coli* O157:H7, the state would sample at the supplier of the source materials used in the production lot that was positive for *E. coli* O157:H7.

- IPP are to inform the establishment management that it is responsible for supporting its basis for defining what product is represented by the sample (i.e., the sampled lot). The establishment can identify the sampled lot for bench trim as limited to the production lot of bench trim only, and not primal cuts or intact steaks and roasts, because the latter products would not be adulterated if positive for *E. coli* O157:H7.

Attachment 5

Supplier and Source Material Information for the Sampled Lot Collected by IPP at the Time of Ground Beef or Bench Trim Sample Collection

A. Supplier information used in the production of the sampled lot if the establishment produces the source materials in-house:

1. Confirmation exists that it was produced in-house (establishment name and number);

2. Lot numbers or slaughter dates;

3. Production dates including slaughter production days if available;

4. Name of the beef components used in the production of the sampled product (e.g., beef trimmings, subprimal cuts, beef hearts, veal trimming, weasand, head or cheek meat) or any information that clearly identifies the source material used;

5. Information on the label of the source product; and

NOTE: IPP can keep the actual label from empty packages.

6. Approximate amount of the beef component produced in each lot (in lbs).

B. Supplier information from each supplier used in the production of the sampled lot if the establishment uses the source materials from a domestic outside source:

1. Establishment name and number;

2. Establishment phone number;

3. Establishment point of contact:

a. Name;

b. Title;

c. E-Mail address; and

d. Fax number:

4. Supplier lot numbers or slaughter dates;

5. Production dates;

6. Name of the beef components used in the production of the sampled product (e.g., beef trimmings, subprimal cuts, beef hearts, veal trimming, weasand, head or cheek meat or any information that clearly identifies the source material used). Collect information from the label of the product; and

NOTE: IPP can keep the actual label from empty packages.

7. Approximate amount of the beef component produced in each lot (in lbs).

ATTACHMENT 6.

HOW TO ACCESS THE OPTIONAL VIDEO TRAINING COURSES: *STEC SAMPLING OF DOMESTIC RAW BEEF*

STEC Sampling of Domestic Raw Beef Products
https://www.youtube.com/watch?v=BlV_GpoTpUU&feature=youtu.be

You can also access this training on AGlearn.